

LEAD WITH DISSOLVABLE COATING FOR IMPROVED FIXATION AND EXTRACTION

Cross-Reference to Related Application(s)

This application is a continuation of U.S. Patent Application No.
5 09/906,571, filed on July 16, 2001, which is a continuation of U.S. Patent
Application No. 09/280,096, filed on March 29, 1999, now issued as U.S. Patent
No. 6,304,786, the specifications of which are incorporated herein by reference.

Technical Field

10 This invention relates generally to electrical leadwires and particularly, but
not by way of limitation, to a cardiac rhythm management system providing an
endocardial cardiac rhythm management lead with an at least partially dissolvable
coating on at least portions of an insulating lead body for improved fixation and
extraction.

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Background

When functioning properly, the human heart maintains its own intrinsic
rhythm, and is capable of pumping adequate blood throughout the body's circulatory
system. However, some people have irregular cardiac rhythms, referred to as
20 cardiac arrhythmias. Such arrhythmias result in diminished blood circulation. One
mode of treating cardiac arrhythmias uses drug therapy. Drugs are often effective at
restoring normal heart rhythms. However, drug therapy is not always effective for
treating arrhythmias of certain patients. For such patients, an alternative mode of
treatment is needed. One such alternative mode of treatment includes the use of a
25 cardiac rhythm management system. Such systems are often implanted in the
patient and deliver therapy to the heart.

Cardiac rhythm management systems include, among other things,
pacemakers, also referred to as pacers. Pacers deliver timed sequences of low

energy electrical stimuli, called pace pulses, to the heart, such as via a transvenous leadwire or catheter (referred to as a “lead”) having one or more electrodes disposed in or about the heart. Heart contractions are initiated in response to such pace pulses (this is referred to as “capturing” the heart). By properly timing the delivery of pace pulses, the heart can be induced to contract in proper rhythm, greatly improving its efficiency as a pump. Pacers are often used to treat patients with bradyarrhythmias, that is, hearts that beat too slowly, or irregularly.

Cardiac rhythm management systems also include cardioverters or defibrillators that are capable of delivering higher energy electrical stimuli to the heart. Defibrillators are often used to treat patients with tachyarrhythmias, that is, hearts that beat too quickly. Such too-fast heart rhythms also cause diminished blood circulation because the heart isn’t allowed sufficient time to fill with blood before contracting to expel the blood. Such pumping by the heart is inefficient. A defibrillator is capable of delivering an high energy electrical stimulus that is sometimes referred to as a defibrillation countershock. The countershock interrupts the tachyarrhythmia, allowing the heart to reestablish a normal rhythm for the efficient pumping of blood. In addition to pacers, cardiac rhythm management systems also include, among other things, pacer/defibrillators that combine the functions of pacers and defibrillators, drug delivery devices, and any other systems or devices for diagnosing or treating cardiac arrhythmias.

One aspect of typical cardiac rhythm management systems is providing an appropriate endocardial lead coupling an implantable cardiac rhythm management device to the heart for sensing intrinsic electrical heart activity signals and/or delivering electrical therapy such as pacing stimulations or defibrillation countershocks. In conventional cardiac rhythm management systems, the lead typically includes a distal electrode that is transvenously guided into the right atrium or right ventricle. The electrode is carefully positioned to contact adjacent cardiac tissue for sensing and/or providing therapy. The preferred location provides adequate amplitude sensed intrinsic electrical heart activity signals and low

threshold energy requirements for effectively delivering pacing and/or defibrillation therapy. To ensure that the electrode's location does not change over time in spite of continuous heart contractions, a fixation device may be used to anchor the distal end of the leadwire in position within the heart.

Even if the position of the electrode is stabilized, stimulation thresholds may vary over time as a result of interactions between the electrode and the adjacent tissue. Fibrotic scar tissue may form during the recovery and healing process as the body reacts to the presence of the electrode. The growth of fibrotic tissue results in chronic stimulation energy thresholds that exceed the acute energy thresholds obtained immediately after implant. As a result, higher stimulation energies are required, thereby shortening the usable life of the battery-powered implantable cardiac rhythm management device. By providing a steroid at the electrode and/or its associated fixation device, modified fibrotic tissue is formed and lower chronic stimulation thresholds are obtained, as disclosed in Heil, Jr. et al., U.S. Patent No. 4,819,661, which is assigned to the assignee of the present application, and which is incorporated herein by reference in its entirety.

Use of a fixation device to anchor the lead typically obtains consistent chronic sensing and stimulation thresholds, but such fixation devices complicate removal of the lead such as, for example, in the event of an infection or lead failure. For example, removing a lead with a corkscrew or barb fixation device risks damage to the surrounding tissue to which the fixation device is firmly attached. Where such surrounding tissue is fibrotic scar tissue resulting from lead placement and fixation in conjunction with the normal healing process, separation of the lead from the surrounding scar tissue is even more difficult because the lead will likely have become firmly incorporated within the body. Moreover, many such fixation devices are adapted only for securing the distal tip of the lead; they may not adequately secure ring electrodes that are disposed at a slight distance away from the distal tip of the lead. Furthermore, most conventional fixation techniques are directed toward anchoring leads in the right side of the heart. Such techniques may not be as well

suited for anchoring leads elsewhere. Thus, there is a need for providing a cardiac rhythm management lead that is capable of both adequate fixation and removal. There is also a need for providing a cardiac rhythm management lead that is capable of placement and fixation in other regions of the heart, such as within fragile vascular structures.

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Summary

This document describes, among other things, a cardiac rhythm management system providing an endocardial cardiac rhythm management lead with an at least partially dissolvable coating on at least portions of the lead body at or near its distal
10 end, which promotes tissue ingrowth to secure the lead in place within fragile vascular structures or elsewhere. In one embodiment, dissolution of the coating releases a therapeutic agent. In a further embodiment, the therapeutic agent includes a steroid that modifies the fibrotic scar tissue component of tissue ingrowth, such that the resulting bond between the tissue and the lead is weak, such that the lead
15 can be easily extracted if desired.

In one embodiment, the lead includes an insulating elongate body having a proximal and a distal end and a peripheral surface. At least one elongate electrical conductor, having a proximal end and a distal end, is carried within the elongate body. The conductor extends longitudinally along substantially the entire length
20 between the proximal and distal ends of the elongate body. At least one electrode is located at or near the distal end of the elongate body. The electrode is coupled to the distal end of the conductor. The lead also includes an at least partially dissolvable coating on at least portions of the insulating peripheral surface at or near the distal end of the elongate body. The coating provides at least one of a rough surface, a
25 porous surface, and a swollen surface after being exposed to an aqueous substance. Other aspects of the invention will be apparent on reading the following detailed description of the invention and viewing the drawings that form a part thereof.

Brief Description of the Drawings

In the drawings, like numerals describe substantially similar components throughout the several views. Like numerals having different letter suffixes represent different instances of substantially similar components.

Figure 1 is a schematic drawing illustrating generally one embodiment of portions of a cardiac rhythm management system and one environment in which it is used.

Figure 2 is a schematic drawing illustrating generally one embodiment of a disposition of distal portions of a lead in a coronary sinus and/or a great cardiac vein.

Figure 3A is a schematic drawing illustrating one embodiment of portions of a lead.

Figure 3B is a schematic drawing illustrating the portions of the lead of Figure 3A after exposure to an aqueous substance.

Figure 4A is a schematic drawing illustrating generally another embodiment of portions of a lead.

Figure 4B is a schematic drawing illustrating the portions of the lead of Figure 4A after exposure to an aqueous substance.

Figure 5A is a schematic drawing illustrating a further embodiment of portions of a lead.

Figure 5B is a schematic drawing illustrating the portions of the lead of Figure 5A after exposure to an aqueous substance.

Figure 6 is a graph of steroid absorbance vs. time, illustrating generally test results for a prototype embodiment of a lead.

Detailed Description

In the following detailed description, reference is made to the accompanying drawings which form a part hereof, and in which is shown by way of illustration specific embodiments in which the invention may be practiced. These embodiments

are described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that the embodiments may be combined, or that other embodiments may be utilized and that structural, logical and electrical changes may be made without departing from the spirit and scope of the present invention.

The following detailed description is, therefore, not to be taken in a limiting sense,
5 and the scope of the present invention is defined by the appended claims and their equivalents. In the drawings, like numerals describe substantially similar components throughout the several views. Like numerals having different letter suffixes represent different instances of substantially similar components.

10 General Overview

This document describes, among other things, a cardiac rhythm management system providing an endocardial cardiac rhythm management lead with an at least partially dissolvable coating on at least portions of an insulating lead body, for improved fixation and extraction.

15 Figure 1 is a schematic drawing illustrating generally, by way of example, but not by way of limitation, one embodiment of portions of a cardiac rhythm management system **100** and one environment in which it is used. In Figure 1, system **100** includes an implantable cardiac rhythm management device **105**, which is coupled via an intravascular endocardial lead **110** to a heart **115** of a human or
20 other patient **120**. System **100** also includes an external programmer **125** providing wireless communication with device **105**, such as by using a telemetry device **130**. Lead **110** includes a proximal end **135**, which is coupled to device **105**, and a distal end **140**, which is coupled on or about one or more portions of heart **115**.

Figure 2 is a schematic drawing illustrating generally, by way of example,
25 but not by way of limitation, one embodiment of an exemplary disposition of distal portions of lead **110**. Figure 2 illustrates chambers of heart **115**, including a right atrium **200**, a right ventricle **205**, a left atrium **210**, and a left ventricle **215**. In the embodiment illustrated in Figure 2, distal end **140** of lead **110** is transvenously

guided into right atrium **200**, through a coronary sinus **220**, and into a great cardiac vein **225**. This example disposition of lead **110** is useful for delivering pacing and/or defibrillation energy to the left side of heart **115**, such as for treatment of congestive heart failure (CHF) or other cardiac disorders requiring therapy delivered to the left side of heart **115**. Other possible dispositions of distal portions of endocardial lead **110** include insertion into right atrium **200** and/or right ventricle **205**, or transarterial insertion into the left atrium **210** and/or left ventricle **215**.

Figure **3A** is a schematic drawing illustrating generally, by way of example, but not by way of limitation, one embodiment of portions of lead **110**, including its distal end **140** and its proximal end **135**. In this embodiment, intravascular endocardial lead **110** includes a biocompatible flexible insulating elongate body **300** (e.g., including a polymer such as medical grade silicone rubber) for transluminal (i.e., transvenous or transarterial) insertion and access within a living organism such as patient **120**. In one embodiment, slender elongate body **300** is tubular and has a peripheral outer surface of diameter d that is small enough for transluminal insertion into coronary sinus **220** and/or great cardiac vein **225**. An elongate electrical conductor **305** is carried within insulating elongate body **300**. Conductor **305** extends substantially along the entire length between the distal end **140** and proximal end **135** of lead **110**, and this length is long enough for lead **110** to couple device **105**, which is implanted pectorally, abdominally, or elsewhere, to desired locations within heart **115** for sensing intrinsic electrical heart activity signals or providing pacing/defibrillation-type therapy thereto. Elongate body **300** forms an insulating sheath covering around conductor **305**. Conductor **305** is coupled to an electrode **310** at or near distal end **140** of elongate body **300**. Conductor **305** is coupled to a connector **315** at or near proximal end **135** of elongate body **300**. Device **105** includes a receptacle for receiving connector **315**, thereby obtaining electrical continuity between electrode **310** and device **105**.

Electrode **310**, or at least a portion thereof, is not covered by the insulating sheath of elongate body **300**. The embodiment of Figure **3A** includes a ring or ring-

like electrode **310** that provides an exposed electrically conductive surface around all, or at least part of, the circumference of lead **110**. In one embodiment, the exposed surface of electrode **310** is smooth. In another embodiment, the exposed surface of electrode **310** is not smooth, thereby allowing tissue ingrowth into interstitial spaces of electrode **310**. In one example, electrode **310** is a coiled wire electrode that is wound around the circumferential outer surface of lead **110**. Lead **110** also includes other configurations, shapes, and structures of electrode **310**.

Lead **110** includes a biocompatible coating **320** on at least one insulating portion of the peripheral surface of elongate body **300** at or near distal end **140**. In one embodiment, as illustrated in Figure **3A**, coating **320** extends circumferentially completely (or at least partially) around the tubular outer peripheral surface of lead **110**. In the embodiment of Figure **3A**, coating **320** occupies one or more nonelectrode regions (i.e., insulating portions of the lead body) extending along a length *l* from the tip of distal end **140** of lead **110**, where length *l* is approximately equal to a distance within coronary sinus **220** and great cardiac vein **140** into which distal end **140** of lead **110** is inserted. In a further embodiment, coating **320** also overlaps one or more portions of one or more electrodes, such as electrode **310**, providing an insulating covering that reduces the exposed surface area of the electrode **310**.

According to one aspect of the invention, coating **320** is at least partially dissolvable when exposed to an aqueous substance such as blood or bodily fluids. In one embodiment, coating **320** provides a substantially smooth low friction outer surface before dissolution of portions of coating **320**. After being exposed to an aqueous substance, however, portions of coating **320** dissolve. According to one aspect of the present system, this dissolution initially makes distal end **140** of lead **110** more slippery, making it easier to insert into patient **120**. After portions of coating **320** dissolve, remaining substrate portions of coating **320** provide a rough and/or porous surface (as illustrated in Figure **3B**) that promotes tissue ingrowth into resulting interstitial regions. Such tissue ingrowth anchors and/or secures lead **110**

to adjacent cardiac tissue, such as within coronary sinus **220** and/or great cardiac vein **225**, or elsewhere in or about heart **115**. In one embodiment, portions of coating **320** undergo osmotic swelling after being exposed to the aqueous substance. This further assists in securing lead **110** within a vascular region such as, for example, within coronary sinus **220** and/or great cardiac vein **225**. Thus, in one
5 embodiment, coating **320** includes a plurality of substantially soluble particles dispersed in a substantially insoluble medium that is adhered to portions of elongate body **300** at or near distal end **140**. When exposed to an aqueous environment, the substantially soluble particles dissolve, leaving behind a rough and/or porous surface that results in tissue ingrowth and/or osmotic swelling, which promotes lead fixation
10 that is particularly well-suited for vascular structures.

In another embodiment, coating **320** includes a therapeutic agent such as, by way of example, but not by way of limitation, a drug, a steroid, a corticosteroid, an antibiotic, and/or an antirejection agent. In one example, the therapeutic agent is provided by the substantially soluble particles that are dispersed in the substantially
15 insoluble medium. In one example, coating **320** includes substantially soluble particles of a steroid such as dexamethasone acetate. When coating **320** is exposed to an aqueous environment, the substantially soluble steroid elements dissolve, providing sustained release into the surrounding tissue. This delays local protein synthesis and tissue healing, which modifies the formation of normal fibrotic scar
20 tissue during the recovery and healing process. As a result, a lesser amount of strongly-bound fibrotic tissue is formed during tissue ingrowth into interstices provided by the rough and/or porous surface of the remaining insoluble portion of coating **320**. The resulting ingrown tissue promotes adequate anchoring and fixation of lead **110**. Because the ingrown tissue includes modified fibrotic scar tissue,
25 however, it is easier to separate lead **110** from the surrounding tissue by pulling and/or turning the lead **110** during removal. Stated differently, steroid release from the structure receiving tissue ingrowth on an insulating portion of elongate body **300** results in friable tissue ingrowth that is more easily disrupted or separated from lead

110 upon extraction and removal of lead 110. Thus, lead 110 offers advantages for both its fixation and removal. Furthermore, reduced pacing and defibrillation threshold energies may be obtained by providing the therapeutic agent near electrode regions, as discussed above.

In a further embodiment, coating 320 provides a therapeutic agent including
5 more substantially soluble dexamethasone sodium phosphate particles. These particles are dispersed in a substantially insoluble medium, such as biocompatible silicone rubber medical adhesive, other polymer, or other suitable biocompatible adhesive substance. Silicone rubber medical adhesive is permeable by water vapor. As a result, water vapor can reach interior dry pockets of the dispersed soluble
10 particles, allowing such particles to dissolve and be released from coating 320 into the surrounding tissue. Other biocompatible, water vapor permeable, and substantially insoluble adhesive or polymeric media can also be used.

In another embodiment, coating 320 provides a therapeutic agent including more substantially soluble dexamethasone sodium phosphate elements dispersed in
15 the substantially insoluble silicone rubber medical adhesive. This embodiment advantageously provides both friable tissue encapsulation and osmotic swelling.

In yet another embodiment, smooth coating 320 includes a combination of the therapeutically active agents, such as dexamethasone acetate and dexamethasone sodium phosphate, dispersed in the substantially insoluble medium (e.g., silicone
20 rubber). In this embodiment, upon exposure to bodily fluids, rapid initial release of the dexamethasone drug substance occurs predominantly in the form of the more soluble dexamethasone sodium phosphate. Release of the dexamethasone drug substance in the form of dexamethasone acetate also occurs upon exposure to bodily fluids, but does so more slowly. Dissolution and release of the dexamethasone
25 sodium phosphate phase will also result in the development of porous surface structures into which tissue ingrowth can occur. Release of the combined forms of the steroid will also serve to modify the tissue ingrowth producing friable encapsulation.

In yet another embodiment, smooth coating **320** includes a combination of the therapeutically active agent dexamethasone acetate and a more substantially soluble nontherapeutic inert agent, such as mannitol or glycerol. In this embodiment, upon exposure to bodily fluids, both the active and inert agents dissolve. The more substantially soluble inert agent first aids in the initial
5 implantation, by lowering lead friction and making the lead more slippery. Then the inert agent quickly dissolves to generate porous features on the surface of the lead body. Release of the dexamethasone drug substance in the form of dexamethasone acetate also occurs upon exposure to bodily fluids, but does so more slowly, as described above. Release of these combined forms of active and inert additives
10 again serves to modify the tissue ingrowth, providing friable encapsulation.

During manufacture, at least one insulating portion of elongate body **300** is coated with coating **320**. The coating **320** cures such that it adheres to elongate body **300**. Increasing the percentage of soluble particles dispersed in the insoluble medium results in increased roughening and/or porosity after lead **110** is exposed to
15 an aqueous substance during use. However, the percentage of soluble particles dispersed in the insoluble medium is typically not so great as to diminish the adhesive properties of coating **320** or to diminish the integrity of coating **320** after its partial dissolution during its use. In a first embodiment, coating **320** includes up to 40% soluble particles (e.g., dexamethasone, dexamethasone acetate or
20 dexamethasone sodium phosphate) combined with or dispersed in the insoluble medium (e.g., silicone rubber medical adhesive). In a second embodiment, coating **320** includes up to 35% soluble particles (e.g., dexamethasone, dexamethasone acetate or dexamethasone sodium phosphate) combined with or dispersed in the insoluble medium (e.g., silicone rubber medical adhesive). In a third embodiment,
25 coating **320** includes up to 30% soluble particles (e.g., dexamethasone, dexamethasone acetate or dexamethasone sodium phosphate) combined with or dispersed in the insoluble medium (e.g., silicone rubber medical adhesive). In a fourth embodiment, coating **320** includes between 30% - 40% soluble particles (e.g.,

dexamethasone, dexamethasone acetate or dexamethasone sodium phosphate) combined with or dispersed in the insoluble medium (e.g., silicone rubber medical adhesive).

Figure 4A is a schematic drawing illustrating generally, by way of example, but not by way of limitation, another embodiment of lead 110, which is similar in many respects to the embodiment of lead 110 described with respect to Figure 3A. The embodiment of Figure 4A includes a plurality of electrodes, such as ring electrodes 310A-C, and tip electrode 400 at distal end 140 of lead 110. The electrodes 310A-C and 400 are coupled to proximal end 135, such as by a corresponding plurality of conductors 305A-D interconnecting electrodes 310A-C and 400 to individual connectors 315 that are received at corresponding receptacles on device 105. Alternatively, one or more of electrodes 310A-C is tied to one or more others of electrodes 310A-C using one or more shared/common conductors 305A-D.

Interelectrode portions of insulating elongate body 300 of lead 110 are covered with coatings 320A-C, which are at least partially dissolved during use as described above, as illustrated in Figure 4B. In one embodiment, coatings 320A-C elute steroids or other therapeutic agents during dissolution, as discussed above. In a further embodiment, one or more of coatings 320A-C also overlap one or more portions of one or more adjacent electrodes, providing an insulating covering that reduces the exposed surface area of the partially covered electrode. The embodiment of Figures 4A-B also optionally include one or more additional passive or active fixations devices, such as one or more tines 405A-B extending laterally outward from a portion of elongate body 300 at or near tip electrode 400. In one example, tines 405A-B are formed of the same insulating material as elongate body 300.

Figure 5A is a schematic drawing illustrating generally, by way of example, but not by way of limitation, another embodiment of lead 110, which is similar in many respects to the embodiment of lead 110 described with respect to Figure 4A.

The embodiment of Figure 5A includes one or more electrodes, such as coil electrodes 310A-B, which each include wires wound around the peripheral circumference of elongate body 300. Coil electrodes 310A-B provide a nonuniform, rough peripheral surfaces that allow tissue ingrowth into interstitial regions between the individual coil windings for providing improved fixation. Interelectrode coating 320A partially dissolves after implantation, as discussed above, which also allows tissue ingrowth into the substantially insoluble substrate portion of interelectrode coating 320A, as illustrated in Figure 5B. In one embodiment, coating 320A releases a therapeutic agent during dissolution, such as a steroid that modifies the fibrotic scarring content of the tissue ingrowth into the rough/porous substrate portion of coating 320A. The steroid elution from coating 320A also modifies the fibrotic scar tissue content of the tissue that grows into the nearby interstices of electrodes 310A-B. The resulting ingrown tissue is friable. It provides fixation of lead 110, but allows easier lead extraction. In a further embodiment, coating 320A also overlaps one or more portions of one or more electrodes, providing an insulating covering that reduces the exposed surface area of the partially covered electrode. Figure 5A also illustrates an embodiment of lead 110 that includes optional other fixation mechanisms, such as one or more of mesh tip electrode 400 or a helical anchor 500 extending longitudinally outward from tip electrode 400. It is understood that one or more of these or other like fixation mechanisms can be used either alone, or in combination with each other, as desired.

Figure 6 is a graph of steroid absorbance vs. time, illustrating generally, by way of example, but not by way of limitation, test results for a prototype embodiment of lead 110, which is similar to that illustrated in Figure 4A, but including a single tip electrode and 4 ring electrodes. The electrodes were separated by polymeric interelectrode regions coated with silicone rubber medical adhesive that included approximately 10% dexamethasone acetate. Approximately 1.8 milligrams of dexamethasone acetate was released over a period of approximately one week, with some drug release still continuing at one week after

exposure to an aqueous solution as indicated by the slight positive slope of the curve in Figure 6 at that time. In one embodiment, the time period during which the therapeutic agent is released is optimized by proper selection of its aqueous solubility, or by otherwise selecting the appropriate combination of the substantially soluble therapeutic agent, the substantially insoluble binder medium, and an appropriate inert additive.

Conclusion

The above-described system provides, among other things, a cardiac rhythm management system providing an endocardial cardiac rhythm management lead with an at least partially dissolvable coating on insulating portions of the lead body at or near its distal end, which promotes tissue ingrowth to secure the lead in place. In one embodiment, dissolution of the coating releases a therapeutic agent. In a further embodiment, the therapeutic agent includes a steroid that modifies the fibrotic scar tissue content of tissue ingrowth, such that the resulting bond between the tissue and the lead is weak, such that the lead can be easily extracted if desired.

Although the present cardiac rhythm management system is described above with respect to a lead that is disposed within the vasculature of a coronary sinus and/or a great cardiac vein, it is understood that the endocardial lead can be positioned elsewhere within the heart, such as within the right or left atria or ventricles, within other blood vessels, or elsewhere.

It is to be understood that the above description is intended to be illustrative, and not restrictive. Many other embodiments will be apparent to those of skill in the art upon reviewing the above description. The scope of the invention should, therefore, be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.